General

Guideline Title

Guideline on the use of devices for adult male circumcision for HIV prevention.

Bibliographic Source(s)

World Health Organization (WHO). Guideline on the use of devices for adult male circumcision for HIV prevention. Geneva (Switzerland): World Health Organization (WHO); 2013 Oct. 54 p. [71 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The rating schemes for the quality of the evidence (very low, low, moderate, high) and the strength of the recommendations (conditional, strong) are defined at the end of the "Major Recommendations" field.

Key Recommendation

The World Health Organization (WHO) prequalified male circumcision devices are efficacious, safe and acceptable as additional methods of male circumcision for human immunodeficiency virus (HIV) prevention among healthy men 18 years and older in high HIV prevalence, resource-limited settings (*conditional, moderate quality evidence*).

This recommendation applies in settings where:

- The devices are used by health-care providers, including physicians and mid-level providers, who are appropriately trained and competent in the use of the specific device.
- Surgical backup facilities and skills are available as appropriate to the specific device.

Quality of the evidence: Moderate

Strength of the recommendation: Conditional in favour of the intervention

Devices prequalified through the WHO programme may include one or more devices with different mechanisms of action. Each specific device will have unique characteristics that must be considered in selection and use. Also, a WHO prequalification decision is time-limited. The products and manufacturing sites included on the WHO list of prequalified male circumcision devices will be reassessed at regular intervals and as warranted. Therefore, it is important to consult information on each device and the list of specific prequalified device(s) available from the WHO Web site

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A recommendation on device use with younger male adolescents (under age 18 years) will be considered when additional data become available.

Strength of the Recommendation

The strength of the recommendation was made based on the quality of the evidence, the balance of anticipated benefits and harms, the values and preferences of clients and health-care providers and resource implications. A conditional recommendation (rather than strong) was made primarily on concerns about potential harms, in particular device slippage and displacements, when devices are used in routine health-care settings, for which there was not yet sufficient evidence. Uncertainty about some aspects of patient acceptability and programme costs also warranted a conditional recommendation.

Definitions:

Significance of the Four Levels of Evidence

Quality	Definition	Implications
High	The guideline development group is very confident that the true effect lies close to that of the estimate of the effect	Further research is very unlikely to change confidence in the estimate of effect
Moderate	The guideline development group is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate
Low	Confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the true effect	Further research is very likely to have an important impact on confidence in the estimate of effect and is unlikely to change the estimate
Very low	The group has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect	Any estimate of effect is very uncertain

Strength of Recommendations

Strong recommendations: With strong recommendations, the guideline communicates the message that the desirable effects of adherence to the recommendation outweigh the undesirable effects. This means that in most situations the recommendation can be adopted as policy.

Conditional recommendations: These are made when there is greater uncertainty about the four factors listed in Table 8.1 in the World Health Organization (WHO) guideline development handbook (see the "Availability of Companion Documents" field) or if local adaptation has to account for a greater variety in values and preferences, or when resource use makes the intervention suitable for some, but not for other locations. This means that there is a need for substantial debate and involvement of stakeholders before this recommendation can be adopted as policy.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Human immunodeficiency virus (HIV) infection

Guideline Category

Prevention

Clinical Specialty

Family Practice

Infectious Diseases

Preventive Medicine

Surgery

Intended Users

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To provide an evidence-based recommendation on the use of adult male circumcision devices for human immunodeficiency virus (HIV) prevention in public health programmes in high HIV prevalence, resource-limited settings
- To present key programmatic considerations for the introduction and use of these devices in public health HIV prevention programmes

Target Population

Adult men (18 years and older) seeking circumcision for human immunodeficiency virus (HIV) prevention in a high HIV prevalence, resource-limited setting

Note: A recommendation on device use with younger male adolescents (less than age 18 years) will be considered when additional data become available.

Interventions and Practices Considered

Devices for male circumcision:

- Elastic collar compression device
- Collar clamp device

Major Outcomes Considered

- Eligibility for device circumcision
- Successful circumcision
- Moderate and serious adverse events
- Healing time
- Pain
- Final cosmetic result
- Procedure time

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Retrieving the Evidence

The World Health Organization (WHO) secretariat formulated a comprehensive search strategy in an attempt to identify all studies, regardless of language or publication status (published, unpublished, in press, or in progress), relevant to the safety, efficacy and acceptability of male circumcision (MC) devices. These are detailed in Annex 1 (see the "Availability of Companion Documents" field).

In addition to conducting online searches for relevant studies using common electronic databases, the WHO secretariat contacted investigators known to be studying the use of MC devices in African countries. Unpublished confidential reports of completed studies and interim reports of on-going studies were made available to WHO for review by the WHO Technical Advisory Group on Innovations in Male Circumcision (TAG). The study investigators provided clarifications where necessary.

Additional evidence to inform values and preferences, resource use and costs was based on literature reviews in PubMed and contact with key investigators. Key stakeholders and experts within the guideline development groups were contacted for their opinions regarding the acceptability of MC devices compared with that of surgical MC.

Number of Source Documents

- 13 total studies were included in the review
- 2 conference results

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Significance of the Four Levels of Evidence

Quality	Definition	Implications
High	The guideline development group is very confident that the true effect lies close to that of the estimate of the effect	Further research is very unlikely to change confidence in the estimate of effect
Moderate	The guideline development group is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate
Low	Confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the true effect	Further research is very likely to have an important impact on confidence in the estimate of effect and is unlikely to change the estimate

Quality	Definition	Implications
Very low	The group has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect	Any estimate of effect is very uncertain

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Selection of Studies and Evidence Synthesis

The World Health Organization (WHO) Technical Advisory Group on Innovations in Male Circumcision (TAG) reviewed evidence from research on the two types of devices for which there was sufficient data to assess clinical efficacy and safety according to the *WHO Framework for the clinical evaluation of devices for male circumcision*. The Framework requirements include:

- Initial studies to establish the safety and acceptability of the device
- At least two independent randomized controlled trials (RCTs) comparing the device with an established method of surgical circumcision performed by providers skilled to offer either method of male circumcision in settings of intended final use
- At least two field studies on the device involving relevant populations and types of facilities, performed by suitably trained and qualified mid-level or non-physician providers in settings of intended final use.

The WHO secretariat, with inputs from the TAG, used the data from the individual eligible studies to generate an estimate of effect for each of the priority outcomes. Insufficient data were available to evaluate any other devices.

Rating the Evidence

The WHO secretariat, with inputs from methodologists, used the GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology to rate the quality of evidence (high, moderate, low or very low) for the critical outcomes (see the "Rating Scheme for the Strength of the Evidence" field). In keeping with the GRADE approach, evidence profiles were prepared. Evidence that was based on RCTs was generally classified as high quality, but the rating was downgraded if the WHO secretariat judged that there was a risk of bias, inconsistency of results, indirectness of evidence, imprecision or publication bias. The evidence from observational studies was not formally categorized but was used to support and supplement the evidence obtained from the randomized studies.

The Evidence

The evidence used to inform the recommendation was restricted to data on devices that met the full set of required studies as detailed in the Framework for clinical evaluation of devices for male circumcision. The evidence included data on two devices of different types: one collar clamp device and one elastic collar compression device. Two evidence profile tables can be found in Annex 2 (see the "Availability of Companion Documents" field), one for each device. For each type of device and for each priority outcome, the table provides estimates of effect generated from the data pooled across the studies. These tables reference the individual studies from which data were extracted to generate each estimate. Key points on each costing study reviewed are also included in Annex 2 (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The guidelines were developed according to World Health Organization (WHO) standards and requirements for guideline development (see the "Availability of Companion Documents" field).

Establishing Guideline Groups

Three groups were set up to develop the guidance:

- The WHO Guideline Steering Group on Male Circumcision Devices, chaired by the WHO Department of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), to lead the guideline development process
- The Guideline Development Group, composed of external content experts, national HIV programme managers, economists and representatives of civil society, to provide inputs throughout all stages of the guideline development process
- The External Review Group, composed of individuals interested in male circumcision for HIV prevention, to provide inputs and perspectives at selected stages of the guideline development process and review the final draft of the guidance.

The WHO Technical Advisory Group on Innovations in Male Circumcision (TAG) is an established advisory group of the Department of HIV/AIDS; it provides advice on technical innovations in male circumcision (MC), the type and quality of evidence required for evaluation, identifies further research needed, and it reviews data from clinical studies. A face-to-face meeting of the TAG took place in January 2013 for an in-depth review of data on the safety, efficacy and acceptability of the two MC devices for which sufficient data were available. At that meeting the TAG also advised WHO on key programmatic considerations that guidance should address. The TAG was represented in both the Guideline Development and External Review Groups to ensure an accurate understanding and consideration of the TAG's assessment and conclusions in the final recommendation and programmatic considerations.

Defining the Scope of the Guidance

The WHO Steering Group and the Guideline Development Group agreed on the scope of the guideline and on the key question and outcomes that would guide the search for and the analysis of evidence and the drafting of the resulting recommendation(s). The key question was:

- *Among adolescent[1] and adult men seeking circumcision for HIV prevention in a high HIV prevalence, resource-limited setting, are male circumcision devices a safe, efficacious and acceptable method for circumcision compared with conventional surgical male circumcision?*

Clinical trials have already established that male circumcision—adequate removal of the foreskin—is highly efficacious in the prevention of heterosexually acquired HIV infection in men, reducing risk by about 60%. Therefore, the current review focused on the efficacy and safety of MC devices to ensure the adequate removal of foreskin and did not address the impact of MC on HIV incidence.

[1]Adolescents are defined by WHO as young people between the ages of 10 and 19 years. Data were only available on males age 18 years and older, and therefore, the final recommendation is for males 18 years and older.

Prioritizing the Outcomes

A list of potential outcomes of interest was circulated among a subgroup of the Guideline Development and External Review Groups. Each reviewer scored the importance of each outcome on a scale of 1 to 9:

- 1 to 3 to indicate an outcome considered not important
- 4 to 6 to indicate an outcome considered important
- 7 to 9 to indicate an outcome considered critical

The individual scores received were then averaged to determine the relative importance of each outcome. See Section 3 in the original guideline document for more information about prioritizing and defining outcomes.

Developing the Recommendation

With the support of a methodologist, the World Health Organization (WHO) Guideline Steering Group reviewed the evidence profiles and prepared a draft recommendation for consideration by the Guideline Development Group. The Steering Group assessed the strength of the recommendation based on:

- The quality of the evidence (i.e., the confidence in the findings of the studies)
- The balance between anticipated benefits and harms
- The values and preferences of clients and health-care providers (i.e., the acceptability of MC devices)
- Resource use and the cost implications of adding MC devices to existing voluntary medical MC services

The Guideline Development Group and External Review Group reviewed the recommendation. Consensus was reached through e-mail, telephone consultations and two ad hoc meetings held during a sub-regional workshop in Africa.

Producing the Guidance

The WHO secretariat drafted the guidance which includes both the recommendation as well as programmatic considerations. Draft versions of the guidance were circulated to members of the guideline development groups. All responses were considered in the final draft of the guidance. Overall, there was full consensus on the recommendation and the minimal variability was dealt with in small group discussions until consensus was achieved.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Strong recommendations: With strong recommendations, the guideline communicates the message that the desirable effects of adherence to the recommendation outweigh the undesirable effects. This means that in most situations the recommendation can be adopted as policy.

Conditional recommendations: These are made when there is greater uncertainty about the four factors listed in Table 8.1 in the World Health Organization (WHO) guideline development handbook (see the "Availability of Companion Documents" field) or if local adaptation has to account for a greater variety in values and preferences, or when resource use makes the intervention suitable for some, but not for other locations. This means that there is a need for substantial debate and involvement of stakeholders before this recommendation can be adopted as policy.

Cost Analysis

Resource Use and Costs

A systematic search of the literature identified three published studies on resource use and costs, and the authors shared one study in press. The studies were undertaken in Zambia, Uganda, Kenya and Zimbabwe. One study compared the collar clamp device to surgical circumcision; the other studies evaluated costing aspects of the elastic collar compression device. Detailed summaries of the review of each study are included in Annex 2 (see the "Availability of Companion Documents" field). Findings are difficult to compare due to differences in research methods and study settings, including public or private ownership, staff mix and support structures and systems. The inclusion and exclusion of certain indirect costs (or the assumptions underpinning the cost calculation) also differ among the studies. Significant differences in the cost of the device also exist among the studies; one study excluded the cost of the device entirely. In comparing the costs of the device and the surgical methods, none of the studies considered the use of disposable or partly disposable kits in the surgical method although this is a common practice in many countries.

From the review of these four studies, the conclusion regarding use of devices suggests the potential to:

- Reduce human resource costs by shifting the performance of male circumcision (MC) procedures to lower cadres of health-care providers
- Reduce consumable costs other than the cost of the device
- Improve efficiency, particularly by increasing the output rate at a given level of staffing
- Improve the cost effectiveness of MC as a human immunodeficiency virus (HIV) prevention strategy by accelerating the pace at which MC targets are reached and HIV infections are averted

However, there remain many uncertainties including whether there will be sufficient demand to realize potential efficiency gains, many costs are unknown including the cost of the device, and costs are highly contextual and will vary from country to country. These uncertainties warranted a conditional recommendation.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

An External Review Group, composed of individuals interested in male circumcision for human immunodeficiency virus (HIV) prevention, provided inputs and perspectives at selected stages of the guideline development process and reviewed the final draft of the guidance.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for the recommendation (see the "Major Recommendations" field).

The evidence profile tables in Annex 2 (see the "Availability of Companion Documents" field) include a detailed quality assessment for each outcome. The tables include an explicit judgement of each factor that determined the quality of evidence for each outcome.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Benefits of device method include minimal interference with activities of daily living (including work); quick procedure; most likely no need for sutures; minimal or no blood loss; good cosmetic result; with an elastic collar compression device, no need for an injectable anaesthetic.
- The balance of benefits and harms of the recommendation is considered in the original guideline document.

Potential Harms

- Risks of device use include some pain while wearing and transient pain during device removal; while wearing the elastic collar compression device, possible odour and the risk of device displacement with erection or if the client engages in sexual activity (intercourse or masturbation); treatment for displacement may require surgery.
- As devices are rolled out from study to field conditions and with broader use, additional device and adverse events can be expected to occur; these should be reported through post-market surveillance. Examples of device incidents include device malfunctions or failures, potential contamination of a sterile package, problems with packaging and failure to adhere to the instructions for use.
- A smaller proportion of men were eligible for circumcision with a device (93%–98%) than by surgery. Similarly high levels of successful circumcisions were achieved with devices as with conventional surgery. Healing following a device method was by secondary intention and took one to two weeks longer than with surgery. The frequency of adverse events with devices was no higher than with surgery. A few adverse events, namely device displacements or device placement failures, required immediate or urgent surgical intervention to prevent potential long-term serious outcomes. A device-based procedure took less than half as long as surgery, even including the time for removal of the device at the second visit. Trained mid-level providers, including nurses, achieved similar outcomes as trained physicians. The levels of pain reported with devices were similar to or lower than the levels reported with surgery.
- The balance of benefits and harms of the recommendation is considered in the original guideline document.

Qualifying Statements

Qualifying Statements

- The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.
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Implementation of the Guideline

Description of Implementation Strategy

Dissemination of the Guideline

This guidance will be available electronically on the World Health Organization (WHO) website and the Clearinghouse for Male Circumcision for Human Immunodeficiency Virus (HIV) Prevention website. Also, it will be sent electronically to policy-makers, to WHO Regional and Country offices and to programme managers, clinicians and researchers known to be working on the male circumcision intervention for HIV prevention. A limited number of print copies will be available on request through WHO and at national and international conferences. WHO will hold a guideline dissemination workshop in one of the East or Southern African countries and provide technical support to Member States upon request. One measure of the effectiveness of the guideline will be the uptake and safety of medical male circumcision (MC) with device methods through monitoring in national programmes.

Key Programmatic Considerations

Priority countries in East and Southern Africa were able to adopt medical MC as an additional HIV prevention strategy within a few years of the initial recommendation by WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS). However, early adoption of MC as an innovation in HIV prevention was not necessarily followed by rapid scale-up of services. Adoption of an innovation and its scale-up are two distinct processes, each of which should be planned. It may be useful for countries to consider the lessons already learnt from the adoption and scale-up of voluntary medical MC services as an HIV prevention intervention. The following factors have been identified as predicting a viable scale-up of national male circumcision programmes:

- A national focal person, a national policy and operational/implementation strategy in place
- A phased implementation approach, starting with pilot or demonstration sites that involve government and other key stakeholders
- On-going government and community consultations accompanied by increasing country ownership
- Sustained high-level political support and the input of decision-makers to resolve implementation challenges as they arise.

Factors that have constrained the scale-up of national male circumcision programmes have been primarily related to the lack of readiness of the health system to absorb the innovation and the reluctance of the intended clientele—uncircumcised men ages 15–49—to use the services.

See section 6 in the original guideline document for additional discussion of programmatic considerations.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

World Health Organization (WHO). Guideline on the use of devices for adult male circumcision for HIV prevention. Geneva (Switzerland): World Health Organization (WHO); 2013 Oct. 54 p. [71 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Oct

Guideline Developer(s)

World Health Organization - International Agency

Source(s) of Funding

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Guideline Committee

Guideline Development Group

Technical Advisory Group on Innovations in Male Circumcision

Guideline Steering Group

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This guideline was developed by the World Health Organization, Department of HIV/AIDS. The work was coordinated by Julia Samuelson under the guidance of Rachel Baggaley and leadership of Gottfried Hirnschall. The principal writers were Doris Mugrditchian, Tim Farley and Julia Samuelson. Special thanks go to Anna Tynan, Intern, and to Jura Editorial Services SARL.

*Also a member of the Technical Advisory Group on Innovations in Male Circumcision.

Financial Disclosures/Conflicts of Interest

Declaration of interest forms were collected from every member of each guideline development group and the World Health Organization (WHO) Technical Advisory Group (TAG) on Innovations in Male Circumcision according to the established WHO procedures. The main potential conflicts of interest were intellectual. The WHO secretariat determined that there were no conflicts or potential conflicts that would require exclusion from discussions and/or development of the recommendation. The members of the Guideline Development Group who also have a capacity with a donor agency provided inputs as technical experts and were not considered as representatives of their respective donor agencies. At the WHO TAG meeting, only members were present for the final discussion and decisions regarding the clinical efficacy and safety of each specific device that was evaluated.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the World Health Organization (WHO) Web site

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Print copies: Available from the WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland; Phone: +41 22 791 3264; Fax: +41 22 791 4857; E-mail: bookorders@who.int.

Availability of Companion Documents

The following are available:

- Guideline on the use of devices for adult male circumcision for HIV prevention: Annex 1. Evidence search strategies and results. Geneva (Switzerland): World Health Organization (WHO); 2013 Oct. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the World Health Organization (WHO) Web site .
- Guideline on the use of devices for adult male circumcision for HIV prevention: Annex 2. Evidence profile. Geneva (Switzerland): World Health Organization (WHO); 2013 Oct. 11 p. Electronic copies: Available in PDF from the WHO Web site .

- WHO Technical Advisory Group on Innovations in Male Circumcision. Evaluation of two adult devices. Geneva (Switzerland): World Health Organization (WHO); 2013 Jan. 36 p. Electronic copies: Available in PDF form the WHO Web site .
- World Health Organization. WHO Handbook for guideline development. Geneva (Switzerland): World Health Organization (WHO); 2012. 63 p. Electronic copies: Available in PDF from the WHO Web site .

In addition, the WHO standards for quality assurance of male circumcision services are available in Section 6.9.4 in the original guideline document .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on May 19, 2014.

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